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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/780,224 02/09/2001 Petrus W. Roelvink 208859 23460 7590 07/17/2003 LEYDIG VOIT & MAYER, LTD **EXAMINER** TWO PRUDENTIAL PLAZA, SUITE 4900 GUZO, DAVID 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780 ART UNIT PAPER NUMBER

> 1636 DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/780,224	ROELVINK ET AL.
	Examiner	Art Unit
	David Guzo	1636
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status		
1) Responsive to communication(s) filed on <u>25 November 2002</u> .		
2a) This action is FINAL . 2b) ★ Thi	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims		
4) Claim(s) 1,4-7,9-13,15,17-29,31-35,37-39,41,42 and 46-64 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) 1,4-7,9,11-13,15,19-29,31-35,37-39 and 49-55 is/are allowed.		
6)[·] Claim(s) 10,17,18,41,46-48,60-62 and 64 is/are rejected.		
7) Claim(s) 42,56-59 and 63 is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement. Application Papers		
9) The specification is objected to by the Examiner.		
10)⊡ The drawing(s) filed on <u>09 February 2001</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) Patent Application (PTO-152)
S. Patent and Trademark Office		

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Detailed Action

The indicated allowability of claims 41-48 is withdrawn in view of the newly discovered reference(s) to Curiel. Rejections based on the newly cited reference follow.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10, 17, 18, 41, 47-48, 60-62 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Curiel.

Applicants claim a chimeric pIX protein having at least one pIX domain (or a pIX domain consisting essentially of a full-length adenoviral pIX peptide sequence) and a non-native amino sequence encoding a ligand (or an antigen) that binds to a substrate present on a cell surface wherein the non-native amino acid sequence is located internally within the chimeric protein. Applicants also claim a nucleic acid sequence encoding said chimeric pIX protein, an adenoviral capsid containing said protein and an adenoviral vector comprising the aforementioned adenoviral capsid.

Curiel (U.S. Patent 6,555,368, issued 04/29/03, effective filing date of 09/24/99, see whole document, particularly claims 1-9, column 3, lines 39-58; column 4, lines 31-42 and Examples 1 and 4) recites the generation of chimeric adenoviral pIX proteins

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comprising the entire coding sequence of the pIX protein and a non-native amino acid sequence (which can be a tag or single chain antibody capable of recognizing a target on a cell surface; these sequences can also be antigenic) wherein the non-native amino acid sequence is inserted internally into the 3' end of the pIX sequence. Curiel recites the nucleic acid encoding the chimeric pIX protein, capsids containing said chimeric protein and adenoviral vectors comprising said capsids. Curiel et al. therefore teaches the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is vague because it depends from a cancelled claim (#44).

Claims 1, 4-7, 9, 11-13, 15, 19-29, 31-35, 37-39, 49-55 are allowed.

Claims 42, 56-59 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703)

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308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo July 14, 2003 TAMAD GHOO

TAMAH EXAMINER

Lavid Jugo